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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/608,200	06/30/2000	Michael J. Banner	21011.0038U1	1062

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10/21/2003

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EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 10/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/608,200

Applicant(s)

BANNER ET AL

Examiner

Mital B. Patel

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/8/03 has been entered.

Response to Amendment/Arguments

2. Applicant's arguments filed 8/6/03 have been fully considered but they are not persuasive.

3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the system of the present invention has the "ability to evaluate the system's performance, in the context of a particular patient at a particular time, and recommend optimal ventilator control settings" without requiring the physician to select specific ventilator settings or without the use of simulator algorithms to "adjust the mechanics of the system to effect the directions that were selected by the physician", i.e., "the current inventions does not deliver instructions based on predetermined data structures to monitor patient ventilation") are not recited in the rejected claim(s). Furthermore, the claims as recited do not exclude clinician input. Although the claims are interpreted in

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light of the specification, limitations from the specification are not read into the claims.

See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

4. In response to Applicant's arguments with respect to the method claims, the Examiner would like to clarify that "recitations of intended use" argument used by the Examiner in the Office Action was directed to the device/apparatus claims and would also like to point out that the functional language was given weight in both the method and device/apparatus claims.

5. In response to applicant's argument that "Biondi et al do not disclose the currently claimed method and system wherein an intelligence system evaluates output signals and ventilator parameter signals to recommend ventilator control settings", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Please note that Applicant has not set forth structural differences between the intelligent system of the present invention versus the intelligent system that is taught by Biondi.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 39-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Biondi et al (US 6158432).

8. **As to claim 39**, Biondi teaches a method for monitoring ventilation support for a patient having an airway, wherein the method comprises providing a monitoring system comprising a plurality of measuring sensors **19, 11, 9, 7** adapted to monitor the patient, or to monitor a breathing circuit coupled to the airway of the patient, each measuring sensor generating an output signal, and an intelligence system (**Col. 5, lines 30-42**) adapted to receive the at least one of the output signals, wherein the intelligence system evaluates at least one output signal to determine the appropriateness of ventilation for the patient; receiving into the intelligence system at least one of the output signals; implementing the intelligence system to evaluate the at least one output signal to determine the appropriateness of ventilation for the patient; and recommending a setting for at least one of the plurality of ventilator setting controls based on the evaluation of the at least one output signal by the intelligence system.

9. **As to claim 40**, Biondi teaches a method further comprising providing a ventilator **17** adapted to supply a gas to a patient via a breathing circuit in fluid communication with at least one lung of the patient, wherein the ventilator is operatively connected to the intelligence system, and wherein the ventilator includes a plurality of ventilator setting controls **10**, wherein each ventilator setting control controls a parameter relating to the supply of gas from the ventilator to the patient.

10. **As to claim 41**, Biondi teaches a method further comprising causing the ventilator to generate a ventilator parameter signal indicative of a parameter related to the supply of gas from the ventilator to the patient; and providing the ventilator parameter signal to the intelligence system, wherein the intelligence system evaluates the at least one output signal and the ventilator parameter signal to determine the appropriateness of ventilation.

11. **As to claim 42**, Biondi teaches a method further comprising adjusting at least one plurality of ventilator setting controls based on the setting determined in the recommended step.

12. **As to claim 43**, Biondi teaches a method further comprising wherein the output signals are selected from the group consisting of an exhaled carbon dioxide signal indicative of the exhaled carbon dioxide (ExCO₂) level of the exhaled gas expired by the patient within the breathing circuit; a flow rate signal indicative of the flow rate (V) of the inhaled/exhaled gas expired by the patient within the breathing circuit; a pulse oximeter hemoglobin oxygen saturation (SpO₂) signal indicative of the oxygen saturation level of the patient; a pressure (P) signal indicative of the pressure of the

breathing gas within the breathing circuit; a blood pressure (BP) signal indicative of the blood pressure of the patient; and a temperature (T) signal indicative of the core body temperature of the patient (**See Col. 11**).

13. **As to claim 44**, Biondi teaches a method wherein the output signals also include at least one of the group consisting of an arterial blood gas PaO₂ signal; an arterial blood gas PaO₂ signal; and an arterial blood gas pH signal(**See Col. 11**).

14. **As to claim 45**, Biondi teaches a method wherein the ventilator parameter signals include at least one of the group consisting of a minute ventilation (V_E) signal; a ventilator breathing frequency of (f) signal; a tidal volume (V_T); a breathing gas flow rate (V) signal; a pressure limit signal; a work (WOB) signal; a pressure support ventilation (PSV) signal; a positive end expiratory pressure (PEEP) signal; a continuous positive airway pressure (CPAP) signal; and a fractional inhaled oxygen concentration (FIO₂) signal (**See Col. 11**).

15. **As to claim 46**, Biondi teaches a method further comprising displaying the recommended settings of the ventilator setting controls (**See Col. 4, lines 9-19**).

16. **As to claim 47**, Biondi teaches a method wherein the intelligence system comprises a neural network **212**, and wherein recommending the settings of the ventilator setting controls of the ventilator comprises applying at least a portion of the output signals and the ventilator parameter signals to the neural network of the intelligence system to determine the recommended settings of the ventilator setting controls.

17. **As to claim 48**, Biondi teaches a method further comprising selecting output signals for display; and displaying the selected output signals in real time (**See Col. 6, line 11**).

18. **As to claim 49**, Biondi teaches a method further comprising displaying at least one of the recommended ventilator setting control settings.

19. **As to claim 50**, Biondi teaches a method wherein the intelligence system is programmed with a set of decision rules **142, 144**.

20. **As to claim 51**, Biondi teaches a monitoring system comprising a plurality of measuring sensors **19, 11, 9, 7** adapted to monitor the patient, or to monitor a breathing circuit coupled to the airway of the patient, wherein each measuring sensor generates an output signal; and an intelligence system (**Col. 5, lines 30-42**) adapted to receive the at least one of the output signals, wherein the intelligence system evaluates at least one output signal to determine the appropriateness of ventilation for the patient.

21. **As to claim 52**, Biondi teaches a system further comprising a ventilator **17** operatively coupled to the intelligence system, wherein the ventilator is adapted to supply a gas to a patient via a breathing circuit in fluid communication with at least one lung of the patient, wherein the ventilator includes a plurality of ventilator setting controls **10**, and wherein each ventilator setting control controls a parameter relating to the supply of gas from the ventilator to the patient.

22. **As to claim 53**, Biondi teaches a system wherein the ventilator is adapted to generate a ventilator parameter signal indicative of a parameter related to the supply of gas from the ventilator to the patient, and wherein the intelligence system evaluates the

at least one output signal and the ventilator parameter signal to determine the appropriateness of ventilation.

23. **As to claim 54**, Biondi teaches a system wherein the ventilator is configured and arranged such that at least one plurality of ventilator setting controls is adjusted based on a result of the evaluation of the at least one output signal.

24. **As to claim 55**, Biondi teaches a system further comprising an output device **24** (**See also Fig. 5**) operatively coupled to the intelligence system, wherein the output device is adapted to present a result of the evaluation of the at least one output signal in a human-perceivable format.

25. **As to claim 56**, Biondi teaches a system wherein the plurality of ventilation support parameters is selected from the group consisting of a flow rate flow rate (V) of the inhaled/exhaled gas expired by the patient within the breathing circuit ; exhaled carbon dioxide (ExCO₂) level of the exhaled gas expired by the patient within the breathing circuit; hemoglobin oxygen saturation (SpO₂) level of the patient; pressure (P) of the breathing gas within the breathing circuit; blood pressure (BP) of the patient; and core body temperature (T) of the patient (**See Col. 11**).

26. **As to claim 57**, Biondi teaches a system wherein the plurality of ventilation support parameters also includes at least one of the group consisting of an arterial blood gas PaO₂ level of the patient; an arterial blood gas PaO₂ level of the patient; and an arterial blood gas pH level of the patient (**See Col. 11**).

27. **As to claim 58**, Biondi teaches a system wherein the plurality of ventilation support parameters include at least one of the group consisting of a minute ventilation

(V_E) signal; a ventilator breathing frequency of (f) signal; a tidal volume (V_T); a breathing gas flow rate (V) signal; a pressure limit signal; a work (WOB) signal; a pressure support ventilation (PSV) signal; a positive end expiratory pressure (PEEP) signal; a continuous positive airway pressure (CPAP) signal; and a fractional inhaled oxygen concentration (FIO₂) signal (**See Col. 11**).

28. **As to claim 59**, Biondi teaches system further comprising an alarm (**Col. 5, line 49**) for notifying an operator that the setting of at least one ventilator setting controls differs from the recommended settings.

29. **As to claim 60**, Biondi teaches a system wherein the intelligence system comprises at least one neural network **212**.

30. **As to claim 61**, Biondi teaches a system wherein the intelligence system is programmed with a set of decision rules **142,144**.

31. **As to claim 62**, Biondi teaches a system wherein the system has means **222** for training the neural network .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

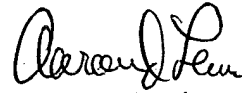
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp



Aaron J. Lewis
Primary Examiner